Memo of Meeting

Date: February 22, 2001

Location: 1350 Piccard Drive
Rockville, MD

Subject: 21 Code of Federal Regulations, Part 11; Electronic Records; Electronic Signatures

Representing Qumas, Inc.:

Mr. Kevin O'Leary, President

Ms. Valarie Bailey, Vice President

Representing FDA:

Mr. Paul Motise, Consumer Safety Office, Office of Enforcement

Ms. Christine Nelson, Consumer Safety Officer, Office of Health and Industry Programs, Center for Devices and Radiological Health

Mr. Mark Hackman, Consumer Safety Officer, Center for Food Safety and Applied Nutrition

Mr. Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological Health

The meeting was held at Mr. O'Leary's request to familiarize FDA with his company's software that is intended to enable firms to modify certain applications so that they would have part 11 compliant features. The features include use of electronic signatures, signature manifestations, and audit trails.

At the start of the meeting we explained that FDA doesn't approve/disapprove part 11 products and services and that our comments should not be taken as formal FDA review. We commented that we were interested in knowing about available enabling technologies, including add-ons to existing systems that lack certain part 11 technical features.

Background:

By way of background, Mr. O'Leary explained that Qumas had its origins in Ireland (a major software exporter). He commented that his firm surveyed industry needs and then focused on document management. He explained that 55 FDA regulated entities now use Qumas applications. The main product we discussed at this meeting is a document management system that resides on top of three major applications – Oracle, Documentum, and Lotus Notes.

Qumas Applications:

During the meeting Mr. O'Leary demonstrated the product on a laptop computer. He showed how the software implements electronic signatures, signature manifestations (signer's printed name, date/time of signing and signature meaning) and audit trails. He briefly explained the basic architecture of how the software integrates with the major commercial applications; a graphical user interface communicates, via a provider's interpreter, with a records database repository.

We commented that many FDA regulated entities are small companies that don't use large applications like Oracle, Documentum or Lotus Notes, and that it would be helpful to such firms if a Qumas product could be prepared for smaller stand alone applications such as MS Access. Mr. O'Leary commented that the general demand was not yet large enough. We said that FDA regulated industries constitute a considerable segment of commerce (with one fourth of every consumer dollar spent on something that FDA regulates.) We added that we expect demand to grow very quickly as other agencies develop and issue regulations similar to part 11 as they implement the Electronic Signatures in Global and National Commerce Act, and the Government Paperwork Elimination Act.

Validation:

Regarding validation, Mr. O'Leary described the validation services his firm provides, including system documentation and test scripts. We asked if his firm would permit customers to audit their operations as part of the validation effort. He said yes, and that Qumas participates in the PDA's vendor audit program.

Training:

Mr. O'Leary also explained that his firm offers a variety of training services, from CD-based interactive programs to on-site hands-on PC based instruction. He offered to assist FDA by training agency investigators – for example, by showing

them examples of how part 11 requirements such as audit trails, are being implemented. He mentioned that he could arrange for on-site visits to Qumas clients, or could bring a mobile classroom environment (up to 10 PCs) to an FDA facility.

We said we would have to check with our training managers regarding accepting his offer and then get back to him.

We asked if the firm's products worked in conjunction with SAP. Mr. O'Leary said no, and explained that the reason had to do with the software structure of SAP; it does not, according to Mr. O'Leary, have a standard application interface.

The meeting concluded after about two hours.

cc:
Part 11 dockets
HFC-200
HFA-224
FDA Part 11 Committee members
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P. Motise 03/13/01